

What is claimed is:

- 1 1. A catheter adapted for deployment in a body vessel to occlude flow and remove
2 material located distal to the site of occlusion, comprising:
3 an outer elongated hollow shaft configured for introduction into a blood vessel,
4 an expandable occluder at or near the distal end of the outer shaft which substantially
5 isolates a region within the vessel immediately external to the distal portion of the
6 outer shaft from the region within the outer shaft and within the vessel distal to the
7 occluder,
8 an efflux port in communication with the lumen of the outer shaft that provides for the
9 removal of material from the region within the vessel and distal to the outer shaft,
10 an inner elongated and hollow shaft that is able to slide longitudinally within the outer
11 shaft and is terminated distally with one or more openings that allow the contents of
12 the inner shaft to exit its lumen and enter the vessel distal to the occluder in a pattern
13 of flow determined in part by the arrangement of the one or more openings,
14 an influx port in fluid communication with the lumen of the inner shaft, and
15 a treatment port that provides access to the lumen of the outer shaft.
- 1 2. The device of claim 1, wherein the expandable occluder is inflatable and is connected
2 to an inflation lumen incorporated into a wall of the outer elongated shaft.
- 1 3. The device of claim 1, wherein the expandable occluder is inflatable and is connected
2 to an inflation lumen extending through a separate, hollow elongated shaft that runs
3 parallel to the outer elongated shaft.
- 1 4. The device of claim 1, wherein the expandable occluder is inflatable and is configured
2 to have an inner wall and an outer wall with connections between the inner and outer wall
3 to produce a funnel-shaped structure upon inflation, the funnel-shaped structure having a
4 larger end distal to a smaller end.

1 5. The device of claim 1, wherein the inner shaft is configured to allow passage of a
2 guidewire through the lumen that extends through an opening in the distal wall of the
3 inner shaft, for the purposes of aiding in the delivery of the catheter and treatment or
4 diagnostic means to the site of interest within a blood vessel.

1 6. The device of claim 1, wherein the expandable occluder is self-expanding.

1 7. The device of claim 1, wherein the expandable occluder comprises open-cell foam
2 surrounded by an airtight sheath and the open-cell foam is in fluid communication with
3 an inflation lumen incorporated into the wall of the outer elongated shaft

1 8. The device of claim 1, wherein the expandable occluder comprises open-cell foam
2 surrounded by an airtight sheath and the open-cell foam is in fluid communication with
3 an inflation lumen in a separate, hollow elongated shaft that runs parallel to the outer
4 elongated shaft.

1 9. The device of claim 1, further comprising means for varying rates of fluid flow
2 through the influx port and/or the outflux port over time in a manually controlled or
3 programmed fashion.

1 10. The device of claim 1, further comprising means for inducing fluid flow within the
2 vessel at or near the treatment site at physiologically relevant flow levels.

1 11. The device of claim 1, further comprising a stent delivery catheter introduced through
2 the treatment port and the lumen of the outer shaft.

1 12. The device of claim 1, further comprising an angioplasty catheter introduced through
2 the treatment port and the lumen of the outer shaft.

1 13. The device of claim 1, further comprising a distal embolic protection device
2 introduced through the treatment port and the lumen of the outer shaft.

1 14. The device of claim 1, further comprising a distal embolic filter introduced through
2 the treatment port and the lumen of the outer shaft.

1 15. The device of claim 1, wherein the lumen of the inner shaft is sized and configured
2 for passage of a guidewire.

1 16. The device of claim 1, wherein the lumen of the inner shaft is terminated on a distal
2 end by a flexible seal configured to allow passage of a guidewire and to form a fluid tight
3 seal around the guidewire.

1 17. The device of claim 1, further comprising a guidewire fixedly attached to a distal end
2 of the inner shaft.

1 18. A catheter adapted for deployment in a body vessel to occlude flow and remove
2 material located distal to the induced occlusion, comprising:
3 an outer elongated and hollow shaft configured for introduction into a blood vessel,
4 a middle elongated and hollow shaft free to slide within the outer shaft and that
5 terminates in a self-expanding funnel shaped structure,
6 an expandable occluder at or near the distal end of the outer shaft which substantially
7 isolates the region within the vessel immediately external to the distal portion of the
8 outer shaft from the region distal to the occluder and outside of the middle shaft,
9 an efflux port in communication with a lumen of the middle shaft that provides for the
10 removal of material from the region within the vessel and distal to the middle shaft,
11 an inner elongated and hollow shaft that is able to slide within the outer shaft and is
12 terminated distally with at least one opening that allows fluid flowing through a
13 lumen of the inner shaft to exit the lumen and enter the vessel distal to the self-
14 expanding funnel,

15 an influx port in fluid communication with the lumen of the inner shaft, and
16 a treatment port that provides access to the lumen of the middle shaft.

1 19. The device of claim 18, wherein the expandable occluder is inflatable and is
2 connected to an inflation lumen incorporated into a wall of the outer elongated shaft.

1 20. The device of claim 18, wherein the expandable occluder is inflatable and is
2 connected to an inflation lumen extending through a separate, hollow elongated shaft that
3 runs parallel to the outer shaft.

1 21. The catheter of claim 18, further comprising an additional elongated shaft having a
2 wall located between the middle and outer shafts, and configured to constrain the
3 diameter of the self-expanding funnel shaped structure prior to expansion of the self-
4 expanding funnel shaped structure and to assist in contraction of the self-expanding
5 funnel shaped structure prior to withdrawal of the catheter from the site of interest.

1 22. The device of claim 18, further comprising a guidewire that extends through the
2 lumen of the inner shaft and through an opening in a distal wall of the inner shaft.

1 23. The device of claim 18, wherein the expandable occluder is self-expanding.

1 24. The device of claim 18, wherein the expandable occluder comprises open-cell foam
2 surrounded by an airtight sheath and the open-cell foam is in fluid communication with
3 an inflation lumen incorporated into the wall of the outer elongated shaft

1 25. The device of claim 18, wherein the expandable occluder comprises open-cell foam
2 surrounded by an airtight sheath and the open-cell foam is in fluid communication with
3 an inflation lumen in a separate, hollow elongated shaft that runs parallel to the outer
4 elongated shaft.

3 an outer elongated and hollow shaft configured for introduction into a blood vessel,
4 an expandable occluder at or near the distal end of the outer shaft which substantially
5 isolates the region within the vessel immediately external to the distal portion of the
6 outer shaft from the region within the outer shaft and within the vessel distal to the
7 occluder,
8 an efflux port in communication with a lumen of the outer shaft that provides for the
9 removal of material from the region within the vessel and distal to the outer shaft,
10 an inner elongated and hollow shaft that is able to slide longitudinally within the outer
11 shaft and is terminated distally with one or more openings that allow fluid flowing
12 within a lumen of the inner shaft to exit the inner shaft and enter the vessel distal to
13 the occluder in a pattern of flow determined in part by the arrangement of the one or
14 more openings, and
15 an influx port in fluid communication with the lumen of the inner shaft.

1 35. The device of claim 34, further comprising:

2 a treatment port that provides access to the lumen of the outer shaft.

1 36. The device of claim 34, wherein the at least one opening comprises a multiplicity of
2 openings, the openings being angled in a proximal direction with respect to a longitudinal
3 axis of the inner shaft.

1 37. The device of claim 34, wherein the expandable occluder is inflatable and is
2 connected to an inflation lumen incorporated into a wall of the outer elongated shaft.

1 38. The device of claim 34, wherein the expandable occluder is inflatable and is
2 connected to an inflation lumen extending through a separate, hollow elongated shaft that
3 runs parallel to the outer shaft.

1 39. The device of claim 34, wherein the expandable occluder is inflatable and is
2 configured to have an inner wall and an outer wall with connections between the inner

3 and outer wall to produce a funnel-shaped structure upon inflation, the funnel-shaped
4 structure having a larger end distal to a smaller end.

1 40. The device of claim 34, further comprising a guidewire that extends through the
2 lumen of the inner shaft and through an opening in a distal wall of the inner shaft.

1 41. The device of claim 34, wherein the expandable occluder is self-expanding.

1 42. The device of claim 34, wherein the expandable occluder comprises open-cell foam
2 surrounded by an airtight sheath and the open-cell foam is in fluid communication with
3 an inflation lumen incorporated into the wall of the outer elongated shaft.

1 43. The device of claim 34, wherein the expandable occluder comprises open-cell foam
2 surrounded by an airtight sheath and the open-cell foam is in fluid communication with
3 an inflation lumen in a separate, hollow elongated shaft that runs parallel to the outer
4 elongated shaft.

1 44. The device of claim 34, further comprising means for varying rates of fluid flow
2 through the influx port and/or the outflux port over time in a manually controlled or
3 programmed fashion.

1 45. The device of claim 34, further comprising a source of radiopaque contrast agent in
2 fluid connection with the lumen of the inner shaft.

1 46. A method for therapeutic intervention at a site of interest in a vessel comprising:
2 introducing an occluder to a point in the vessel proximal to the site of interest;
3 deploying the occluder to occlude the vessel proximal to the site of interest;
4 aspirating fluid from the vessel proximal to the site of interest;
5 advancing a rinsing catheter distal to the site of interest;
6 infusing a rinsing solution through the rinsing catheter to the site of interest;

0572068-05101

7 introducing a treatment device to the site of interest;
8 deploying the treatment device;
9 withdrawing the treatment device;
10 disengaging the infusion;
11 disengaging the aspiration; and
12 removing the occluder.

1 47. The method of claim 46, wherein the steps of advancing a rinsing catheter distal to
2 the site of interest and infusing a rinsing solution through the rinsing catheter to the site
3 of interest are performed prior to the steps of introducing a treatment device to the site
4 of interest and deploying the treatment device.

1 48. The method of claim 46, wherein the steps of advancing a rinsing catheter distal to
2 the site of interest and infusing a rinsing solution through the rinsing catheter to the site
3 of interest are performed after the steps of introducing a treatment device to the site of
4 interest and deploying the treatment device.

1 49. The method of claim 46, wherein the rate of aspiration and rate of infusion are
2 chosen to create a volume exchange of fluid at the site of interest.

1 50. The method of claim 46, wherein the rate of aspiration and rate of infusion are
2 chosen to create a rate of volume exchange of fluid at the site of interest in the range of
3 approximately 1:1 to 1:2.

1 51. The method of claim 46, wherein the rate of aspiration and/or rate of infusion vary in
2 intensity over time in order to enhance removal of debris from the site of interest.

1 52. The method of claim 46, comprising inducing fluid flow within the vessel at or near
2 the treatment site at physiologically relevant flow levels for the vessel at the site of
3 interest.

53. A method for therapeutic intervention at a site of interest in a vessel comprising:
introducing an occluder to a point in the vessel proximal to the site of interest;
deploying the occluder to occlude the vessel proximal to the site of interest;
aspirating fluid at a first, low flow rate from the vessel proximal to the site of interest;
advancing a rinsing catheter distal to the site of interest;
infusing a rinsing solution through the rinsing catheter to the site of interest;
introducing a treatment device to the site of interest;
deploying the treatment device;
withdrawing the treatment device;
aspirating fluid at a second, higher flow rate from the vessel proximal to the site of
interest;
disengaging the infusion;
disengaging the aspiration; and
removing the occluder.

54. The method of claim 53, wherein the rate of aspiration and/or rate of infusion vary in
intensity over time in order to enhance the removal of debris from the site of interest.

55. The method of claim 53, comprising inducing fluid flow within the vessel at or near
the treatment site at physiologically relevant flow levels.

56. A method for diagnosing or treating a selected segment of the vasculature that
recovers a substantial proportion of a diagnostic or treatment material that is added to the
vessel lumen to aid in diagnosis or treatment, comprising:
introducing an occluder to a point in the vessel proximal to the selected segment of the
vasculature;
deploying the occluder to occlude the vessel proximal to the selected segment;
advancing a rinsing catheter distal to the occluder;

8 infusing the diagnostic or treatment material through the rinsing catheter to the selected
9 segment;
10 aspirating the diagnostic or treatment material from the vessel proximal to the selected
11 segment;
12 disengaging the infusion;
13 disengaging the aspiration; and
14 removing the occluder.

1 57. The method of claim 56, wherein the rinsing catheter is advanced to a point within
2 the selected segment.

1 58. The method of claim 56, wherein the rinsing catheter is advanced to a point distal to
2 the selected segment.

1 59. The method of claim 56, wherein the diagnostic or treatment material comprises a
2 radiopaque dye.

1 60. The method of claim 56, wherein the rate of aspiration and rate of infusion are
2 chosen to create a volume exchange of fluid at the site of interest.

1 61. The method of claim 56, wherein the rate of aspiration and rate of infusion are
2 chosen to create a rate of volume exchange of fluid at the site of interest in the range of
3 approximately 1:1 to 1:2.

1 62. A method of providing embolic protection at a site of interest in a vessel, comprising:
2 introducing an occluder to a point in the vessel proximal to the site of interest;
3 deploying the occluder to occlude the vessel proximal to the site of interest;
4 aspirating fluid from the vessel proximal to the site of interest;
5 introducing an embolic protection device distal to the site of interest;
6 deploying the embolic protection device;

7 undeploying the occluder; and
8 disengaging the aspiration.

1 63. The method of claim 62, further comprising:
2 advancing a rinsing catheter distal to the site of interest; and
3 infusing a rinsing solution through the rinsing catheter to the site of interest while
4 aspirating fluid from the vessel proximal to the site of interest.

1 64. The method of claim 62, further comprising:
2 advancing a rinsing catheter distal to the site of interest prior to introducing the embolic
3 protection device; and
4 infusing a rinsing solution through the rinsing catheter to the site of interest while
5 introducing the embolic protection device.

1 65. The method of claim 62, further comprising:
2 introducing a treatment device to the site of interest;
3 deploying the treatment device; and
4 withdrawing the treatment device while the embolic protection device is deployed.

1 66. The method of claim 62, further comprising:
2 deploying the occluder to occlude the vessel proximal to the site of interest;
3 aspirating fluid from the vessel proximal to the site of interest;
4 undeploying the embolic protection device;
5 withdrawing the embolic protection device from the site of interest;
6 undeploying the occluder; and
7 disengaging the aspiration.